REMARKS

Applicant is submitting a Request for Continued Examination along with requisite fees concurrently with this Amendment, and thus respectfully requests that the appeal be withdrawn, reopening prosecution of the present application for further consideration in view of same. Currently, claims 74, 75 and 77 are rejected as allegedly anticipated in view of U.S. Patent No. 4,443,441 (Galin I); and claims 74-77 are rejected as allegedly obvious in view of Galin I and U.S. Patent No. 5,612,027 (Galin II). Without acquiescing to the merits of the anticipation and obviousness rejections at issue in this case to date, Applicant has amended the sole independent claim 74 in the spirit of cooperation and an effort to expedite prosecution of the present application. Therefore, Applicant respectfully submits that the anticipation and obviousness rejections of the pending claims should be withdrawn as discussed in further detail below.

As amended, independent claim 74 is directed to an ophthalmic, night vision formulation including, in part, a pharmaceutically active compound consisting essentially of phentolamine in a therapeutically effective amount and in a single dose per day of use so as to effectively disrupt endogenous compounds which stimulate dilator muscles of a human eye thereby effectively reducing pupil size to improve night vision. Support for such amendment can be found in Applicant's specification, for example, at paragraph [0085], indicating "Phentolamine as modified and applied requires a single instillation per day to render up to 20 to 24 hours effect...". Indeed, the "single dose per day of use" requirement is an additional claimed feature distinguished from the primary Galin I reference. In direct contrast, Galin I indicates that "[t]he approximately one drop dose can be repeated several times per day...". See, Galin I, col. 1, lines 49-50. Therefore, Galin I is distinguished from the claimed invention at least in view of same.

Further, Applicant believes that Galin I is distinguished from the claimed invention for additional reasons as previously indicated in this case. For example and in further direct contrast, Galin I indicates that "...the smaller pupil reduces vision, particularly in dim light." See, Galin I, col. 1, lines 37-38. Again, the claimed invention recites that the pharmaceutically active compound consisting essentially of phentolamine is in a therapeutically effective amount and in a single dose per day of use...thereby effectively reducing pupil size to improve night vision. Moreover, Applicant has conducted experiments as detailed in the specification which demonstrate the enhanced benefits to vision by reducing pupil size in dim light (e.g., night

vision) associated with the claimed phentolamine-based formulation as compared to other alpha-1 antagonist-based formulations. See, for example, Applicant's Specification, Examples 1 and 2 and Tables 1 and 2, beginning on page 24.

Indeed, the Table 1 data demonstrates that a phentolamine-based formulation has enhanced effects on pupil reduction, and thus vision, than other types of alpha 1 antagonist-based formulations. This correlates with the Table 2 data, indicating improved vision in dim light due to enhanced pupil reduction, again contrary to what Galin I indicates as discussed above, for example. Such unexpected results as embodied by the claimed invention are further supported by the Affidavit of Gerald Horn, M.D dated October 28, 2007 (Affidavit) and previously submitted in this case, indicating in the Affidavit on pages 1 and 2, at paragraph 4, for example:

> [t]he claimed phentolamine-based formulation inhibits pupillary dilation in scotopic conditions preferentially over constriction of the pupil, affecting the dilator muscles of the iris preferentially, and has no clinically significant effect on the ciliary muscle responsible for accomodation. Therefore, pupil size is optimized to obtain enhanced vision acuity in dim light (e.g., at night) by reducing the pupil diameter in dim light. Moreover, this result was unexpected since conventional ophthalmology indicated that reducing pupil size in dim light would cause vision acuity to deteriorate.

Therefore, Applicant does not believe Galin I provides sufficient teaching to render unpatentable the phentolamine-based ophthalmic solution that improves night vision as presently claimed.

Furthermore, the Patent Office cannot rely solely on Galin II to remedy the deficiencies of Galin I, where Galin II was merely relied on for its alleged teaching regarding the use of viscoelastic agents. Moreover, Applicant believes the anticipation rejection of claims 74, 75, and 77 in view of Galin I is inconsistent with respect to the further alleged obviousness rejection of these same claims in view of Galin I and II, and thus Applicant believes that the anticipation rejection is improper at least in view of same.

Accordingly, Applicant respectfully requests that the anticipation and/or obviousness rejections of Claims 74-77 be reconsidered and withdrawn at least for these reasons, and further respectfully submits that the present application is in condition for allowance.

The Commissioner is hereby authorized to charge deposit account 02-1818 for any fees which are due and owing.

Respectfully submitted,

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